

## Gastrointestinal Stents: Materials and Designs.

Steven John Black, BSc(Hons), PhD<sup>1</sup>

Derek William Edwards<sup>2, 3</sup>

Graham Compton Smith, BSc PhD MInstP CPhys MRSC CChem CSci FRMS<sup>3</sup>

Hans-Ulrich Laasch Dr med, MRCP, FRCR<sup>2, 3</sup>

<sup>1</sup>MDECON Ltd

26 Castle Street

Conwy LL32 8AY

United Kingdom

e-mail: sblack@mdecon.com

<sup>2</sup>Department of Radiology

The Christie NHS Foundation Trust

Manchester M20 4BX

United Kingdom

e-mail: DWE@minnova.uk

<sup>3</sup>Dept. of Natural Sciences

University of Chester

Thornton Science Park

Chester CH2 4NU

United Kingdom

e-mail: graham.smith@chester.ac.uk

Corresponding author

Hans-Ulrich Laasch, Dr med, MRCP, FRCR

Visiting Professor, Dept. of Natural Sciences, University of Chester, Thornton

Science Park, Pool Lane, Chester CH2 4NU, United Kingdom

Email: [HUL@christie.nhs.uk](mailto:HUL@christie.nhs.uk)

Tel +44 161 446 3896

Fax +44 161 446 8532

## Abstract

Over the last 25 years stents have developed into an established way of restoring luminal patency throughout the gastrointestinal tract. Materials used as well as the construction of these devices have become more and more sophisticated in order to comply better with the complex environment they are inserted. The requirements vary greatly from organ to organ and stent behavior differs significantly between stent constructions. However this is not necessarily understood by many operators, as the choice of devices is now vast and in many cases decisions are made on availability and cost. An increasing challenge in malignant conditions is the improving survival of incurable patients, which now exceeds the traditional life expectancy of a stent by a factor of 2 to 3. Consequently more patients experience failure of their stent and require repeat interventions. This has a poor impact on patients' quality of life and potentially on their survival. Re-intervention is often more difficult, carries the risk of additional complications and presents an additional economic burden to the health systems.

This article illustrates current stent designs, their different behavior and their limitations.

## Keywords

Cancer; Dysphagia; Endoprosthesis; Endoscopy; Interventional radiology; Palliation

## Introduction

Since the first case series reporting insertion of a covered metal esophageal in man<sup>1</sup> self-expanding stents have become a mainstay of palliating malignant dysphagia, malignant obstruction of bowel and bile duct and a secondary strategy for managing benign strictures of the gastrointestinal (GI) tract.

The universal concept is of an elastic skeleton, which may have an additional cover applied to stop tissue growing through the interstices and extend patency. Stents are compressed into a tubular delivery system, which has a significantly smaller diameter than the stent, to allow delivery into the narrowed anatomical segment.

Balloon-expandable stents, which are used for blood vessels in the leg and heart are mounted on a dilatation balloon, which is inflated to stretch and deform the collapsed stent into its final configuration and secure the lumen. In contrast self-expanding stents, as used in the GI tract, require sufficient radial force, not only to spring back to their original configuration, but to push back the tissue narrowing the esophagus, bowel or bile duct. This elasticity is provided by a combination of the stent material itself and the construction of the stent.

The surrounding normal mucosal tissue will react to the unexpected ongoing mechanical irritation from movement and friction by “overgranulation”, similar to callus forming on the hands of a builder. The degree and speed of this reaction is highly variable and unpredictable, but as a consequence only fully covered stents must be used in benign disease and generally not left for longer than 6-8 weeks, as they will become non-removable<sup>2</sup>.

In malignant strictures tumor will grow through any gaps in the stent skeleton and eventually over the ends of it, if unchecked by further oncological treatment. Stents covered by a form of plastic stay patent longer than stents made of a bare skeleton,

but are less able to embed and fix themselves within the tumor and may displace with peristalsis. This is probably accelerated if the stent is of a rigid construction, thus presenting more resistance to the peristaltic movement, which is designed to move ingested material forwards. Stents that conform to the anatomy and can absorb peristaltic forces are therefore preferable, particularly in tortuous anatomy. The requirements and challenges to the stent vary between the muscular esophagus, the chemically hostile stomach, the C-shaped duodenum, the delicate structure of the bile duct and the large-caliber colon propelling solid feces. The emerging additional challenge is patient survival. As an example in 2004 the average survival of a British patient requiring an esophageal stent was 90 days<sup>3</sup> but due to evolution of palliative chemotherapy in 2010 this was reaching 1 year, with 5-year survival in T4 tumors coming up to 20%<sup>4</sup> depending on lymph node status, tumor type and whether it carries hormone receptors. As a consequence the requirements for long-term stent performance are ever increasing and current stent designs are becoming inadequate.

## Principles of stent design

While interventionists and even patients are very familiar with the concept of stenting, few are au-fait with the range of different devices and their characteristics. One study has charted the properties of esophageal stents<sup>5</sup>, yet it is unclear what properties make the ideal GI stent. Much focus has been placed on the force with which the stent expands, and to what extent the stent is covered, but other qualities are rarely taken into consideration.

### Definitions

Radial force: The strength with which stent expansion occurs against the surrounding tissue

Axial rigidity: The stiffness of a stent, resisting flexion

Flexibility: The ability to bend without breaking or kinking

Conformability: The ability to align to a given shape without resistance

Stent shortening: The amount of reduction in length as the stent expands from the compressed state in the delivery system to its full unconstrained diameter

Laser-cut stent: A stent cut from a solid tube of metal

Braided stent: A woven construction where the wires cross over each other but do not interlock

Knitted stent: A woven construction where the wires hook around each other, allowing a greater degree of displacement

### Principles of Stent Construction

Laser-cut stents

Laser-cut stents are made by perforating a solid tube of shape-memory metal using a laser until only thin struts remain (Fig. 1). This type of stent was originally designed for use in arteries and it has a very high radial force. Despite being able to be compressed into very thin delivery systems, laser-cut stents shorten the least during expansion, typically less than 10%, which allows for accurate placement. Their drawbacks are a high axial rigidity, with an inherent desire to return to their straight shape. As a result they do not conform well to anatomical flexures, tend to deform their environment to accommodate their straight configuration and – if covered – displace more easily. Rigid stents may exert undue pressure of the stent edges onto the bowel wall, which may lead to necrosis and perforation<sup>6</sup>. The only laser-cut stent for the bowel was withdrawn for this reason. A rigid structure in a mobile environment is exposed to repeated flexion forces and subject to metal fatigue and laser-cut stents have a relatively high reported fracture rate<sup>7-12</sup>.

### Braided Stents

In this traditional woven construction, a single strand of metal wire is wrapped around a metal mandrel, resulting in a “finger catcher” construction (Fig. 2), which is also termed “crossing wire” or “S-weave”. Although very flexible, a braided stent retains a relatively high axial rigidity, with inherently trying to regain a straight configuration. When compressed into the delivery system this type of stent lengthens up to twice its nominal size. Conversely the elongated stent shortens up to 50% on release, depending whether full expansion is achieved. Example: a large diameter 10cm stent may measure up to 20cm in a slim delivery system (Fig. 3). To the unwary operator the markedly increased length of the undeployed stent may lead to unexpected outcomes if the middle stent markers are mistaken for the end markers

or stent shortening does not occur due to very tough surrounding tissues. For covered versions braided stents are usually dipped or sprayed with liquid silicone. However this fixes the wires against each other, preventing displacement and markedly increasing the rigidity of the stent (Fig. 4).

### Knitted stents

Also called “hooked wire” or D-weave construction, knitted constructions are becoming the norm for GI stents. The wire filament is bent around pins inserted into the construction mandrel and looped around other wire segments. The wires can displace not only in a lateral, but also in a longitudinal fashion (Fig. 5), allowing segmental compression and almost completely abolishing the straightening forces. Knitted stents conform to anatomical flexures without embedding their ends in the bowel or bile duct wall. They align coaxially in the lumen, which optimizes function and makes re-intervention easier (Fig. 6). Stent shortening is up to 30%, i.e. a 10cm stent may measure up to 15cm in the delivery system. If knitted stents were covered by dipping in silicone they would lose their conformability and they are usually covered by suturing a membrane to the outside of the skeleton or trapping it between two layers of metal mesh (“double” stent). As this does not fix the wires against each other, conformability is preserved.



### Covered versus uncovered stents

Bare stents have the advantage of embedding into tumor tissue and normal mucosa, resulting in good fixation and very low displacement (“migration”). The trade-off is tissue growing through the mesh, either by proliferation of tumor or benign hypertrophic overgranulation as a result of the chronic trauma to the mucosa. The latter can occasionally be so florid that it may occlude the stent<sup>13</sup>. In case of biodegradable stents it is reversible after the stent has dissolved, but may require dilatation or coagulation<sup>14,15</sup>.

Covered stents are designed to have longer patency rates, as ingrowth can only occur when the cover has perished. Where removal may be necessary, fully covered stents with a retrieval lasso should be used. The lasso acts as a purse string and on traction the end of the stent constricts and the stent can be extracted, either with endoscopic forceps or with dedicated stent extractors (Fig. 7).

A compromise is presented by partially covered stents, where several millimeter of the stent ends are left bare in order to achieve mucosal fixation, while most of the middle is covered (Fig. 8).

Bare and partially covered stents are not designed to be removed. However the tissue, into which the stent has embedded can be obliterated by argon plasma beam coagulation or insertion of a second, covered stent of the same size or larger<sup>16,17</sup>.

After a period of 1-2 weeks the inner stent is extracted and an attempt at removing the original stent can be made. “Stent in stent” removal should only be attempted by experienced operators and ideally using a combination of endoscopy and fluoroscopy to assess stent mobilization and reduce the risk of perforation.

## Stent materials

### Stent skeleton

Stainless steel has been abandoned in favor of super-alloys with markedly improved elasticity and the added benefit of shape memory. By far the commonest is an alloy called nitinol, which is an acronym for Nickel Titanium Naval Ordnance Laboratory. Developed by the US Navy it has found wide application, not just in medicine, but also in household goods such as pop-up tents and dental braces, due to its shape memory.

Shape memory alloys are a class of materials which possess the ability to retain a specific geometry within a fixed temperature range. This property is imparted by through a phase transformation in the crystal structure of the alloy from martensite to austenite phases. In the martensite form at lower temperatures, the metal can easily be deformed into any shape. When the alloy is heated, it goes through transformation from martensite to austenite<sup>11</sup>. In the austenite phase a shape memory alloy remembers the configuration it had before it was deformed. Stents are manufactured by taking the martensite form of the nitinol and forming the stent by laser cutting, weaving or braiding. The stent is then heat treated at a specific temperature to impart shape memory over a set temperature range known as the 'memory transfer temperature' where the austenite form of the alloy is stable. In addition to shape memory nitinol also possesses superelastic properties which allow ductile deformations of up to 25% of the original length without breaking and high tensile strengths making them ideal for stent manufacture. This feature is based on the ability of the atoms to sublux temporarily in the lattice before plastic deformation occurs. For medical devices the memory transfer

temperature is body temperature and is imprinted by baking stents at approximately 500° C before removing them from the mandrel. It is important to understand that the full properties of nitinol only come to play after warming up to body temperature and consequently expansion will continue over several days. Therefore balloon dilatation of stents after deployment is not usually indicated, if a minimum of 25-30% immediate expansion has occurred.

Two non-metallic braided stents are currently in use: A plastic stent (Polyflex, Boston Scientific, Marlborough, Mass., USA) made from a nylon skeleton and a biodegradable stent (SX Ella BD, Ella-CS, Hradec Kralove, Czech Republic) made from polydioxanone, a polymer, which undergoes hydrolysis over 3-4 months. Both materials lack the unique properties of nitinol precluding them from being stored in their delivery systems. These stents need to be loaded manually during the procedure and require large delivery systems.

#### Stent covers and coatings

The currently favored materials are silicone and expanded polytetrafluoroethylene (ePTFE). Silicone, either applied as a solution to braided stents or as a membrane for knitted stents is elastic and relatively bio-resistant and has replaced polyurethane. ePTFE, used as a waterproof membrane in outdoor clothing, has a lower degree of elasticity but is more resilient to the challenging environment of the human body.

Stent coverings are designed to prevent tissue ingrowth from occluding the stent pathway. However, if the wires are fully coated, it may also provide a barrier between the stent skeleton and bodily fluids.

Two further potential benefits are offered by silicone and ePTFE covers; the first is biocompatibility as these coatings reduce the risk of tissue inflammation or mechanical irritation that might occur otherwise. Secondly silicone and ePTFE are effectively nonstick coatings (ePTFE is a derivative of Teflon®) which inhibit the adhesion and growth of yeasts or bacteria which could cause local infection or facilitate local corrosion on the nitinol<sup>18</sup>.

Silicone-dipped stents have the advantage of the metal skeleton being enclosed and protected from potentially corrosive processes. However due to the constant movement of the target organ and the many forces exerted by swallowing, coughing, laughing, hiccups and vomiting the cover invariably becomes detached from the stent skeleton, although the time frame and the exact mechanism of that is unclear. Once the cover is damaged the metal is exposed to the body's chemistry. Subsequently tumor ingrowth can occur, potentially preventing removal of the stent (Fig. 9).

Most interventionists place fully covered stents in the esophagus, in order to prevent rapid re-occlusion. The trade-off is reduced stent fixation, which is particularly important if stents need to be placed across the gastro-esophageal junction (GEJ). Migration rates across the GEJ vary greatly between stents, with an average of around 18% in a national British survey. Manufacturers have tried to address this in different ways with variable results. Partially covered stents may be repositioned immediately after deployment but quickly become fixed by mucosal or tumor ingrowth. One of the most successful designs is a forward facing collar, which acts as an anchor over the top of the tumor (Fig. 10). Stent designs with an outer uncovered segment to allow mucosal fixation (Fig. 11) are intuitively appealing.

However they have the disadvantage of increasing the rigidity of the stent further and the outer segment may become detached. One knitted esophageal stent is currently available, which to some extent absorbs peristaltic forces, reducing migration by providing less resistance to displacing forces (Fig. 12).

For enteral stents the traditional view is that covered versions have unacceptable migration rates. However this relates to a time where only fully covered silicone-dipped stents were available. Partially covered knitted stents were developed to deliver a superior performance, delivering the benefits of a covered stent while remaining conformable<sup>19</sup>. To what extent covered duodenal stents should be avoided in order not to obstruct biliary drainage is not entirely clear. However they certainly preclude future ERCP and this needs to be taken into account.

Similarly the anatomy of the biliary with insertion of the pancreatic and cystic duct and the hilum requires careful consideration if a covered stent is to be placed as it may obstruct drainage from the gallbladder and pancreas. The benefits of covered biliary stents in malignancy are still under debate<sup>20,21</sup>. New biliary stents with a profile that is supposed to allow additional drainage around the outside may address this problem (Fig. 13).

## Stent failure

Primary failure of a stent is rare, often reflecting poor stent position or placement of a rigid stent into tortuous anatomy (Fig. 14).

Secondary failure after initial restoration of patency may be due to obstruction by food, feces or bile sludge, tumor growth into the stent or beyond the stent ends or stent migration.

An emerging problem is stent fracture<sup>22-24</sup> and disintegration due to metal fatigue or corrosion of the metal stent skeleton. This is increasingly observed as improvements in palliative chemotherapy extend patient survival. Stent fractures are most commonly seen in lower esophageal and duodenal stents exposed to gastric acid. They can be observed by the alert operator on routine CT scans (Fig. 15) and should prompt patient re-assessment, as stent removal may become unsafe if the integrity of the stent is lost.

A large amount of stent development has happened by modifying existing devices and applying materials proven safe in other contexts. Furthermore the requirements for device testing vary greatly in different countries but frequently do not involve any clinical trials. A voluntary test often applied, is based on electrolytic corrosion studies of small implants in an artificial laboratory environment (ASTM 2129). The long-term suitability of current stents to the chemically hostile environment of the upper GI tract is unproven.

Patients' life expectancy is ever increasing and due to the plethora of potential difficulties after stent insertion patients need to be kept under review by the inserting team.

## Conclusion

An understanding of the increasing variety of GI stents is essential to allow patients to receive the most appropriate device for their disease and individual anatomy.

Differing stents characteristics need to be matched to the specifics of the patient, the stricture and the life expectancy. Stent materials have not kept up with the increasing survival of the patients requiring stent insertion. Consequently more patients will present with recurrent symptoms requiring re-intervention into a failed stent and need a direct access route to the interventional team.

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## Figures

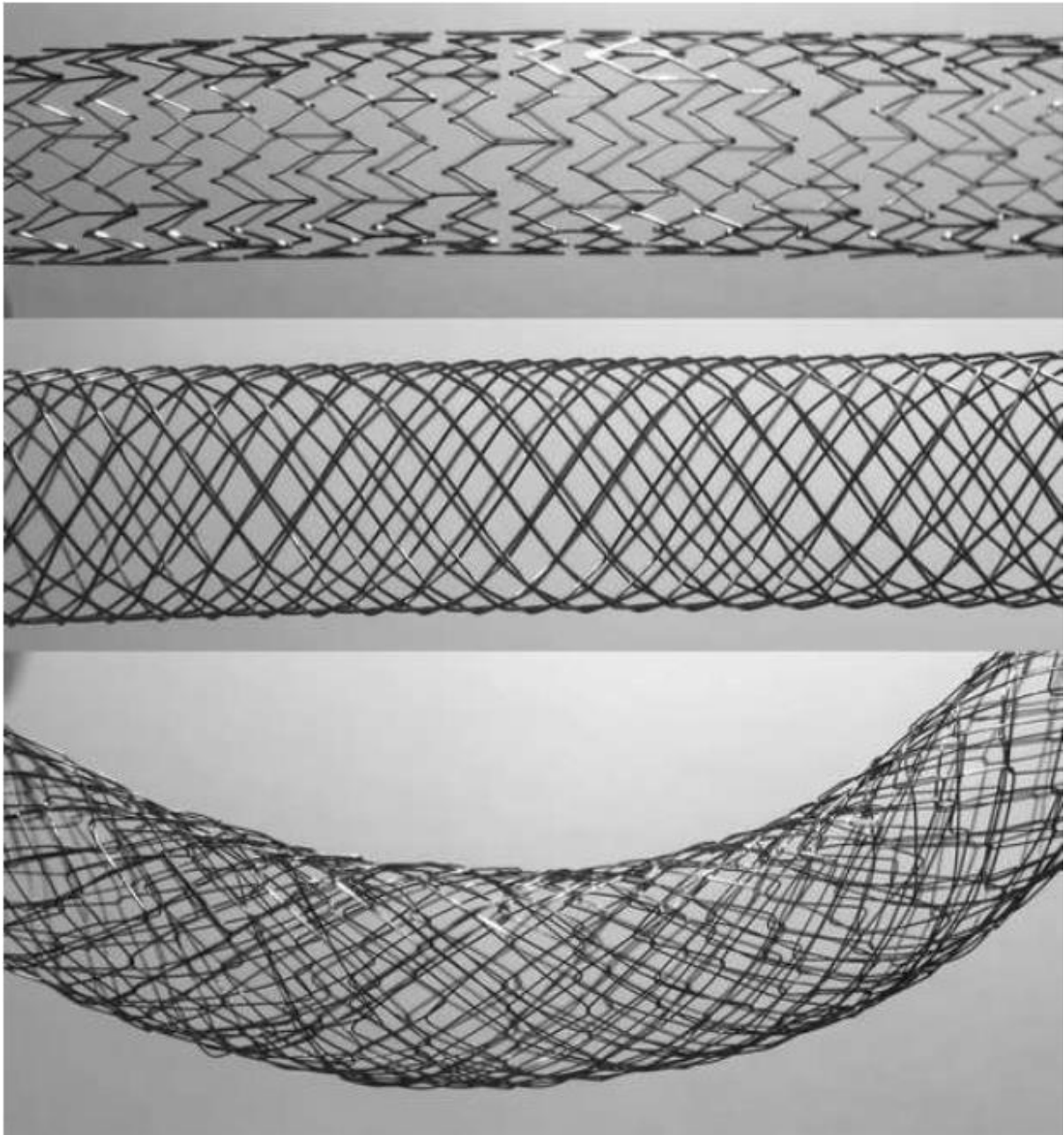


Figure 1: Different construction of biliary stents. From left to right: Laser-cut stent, braided stent with “crossing” wires and knitted stent with “hooked” wires.

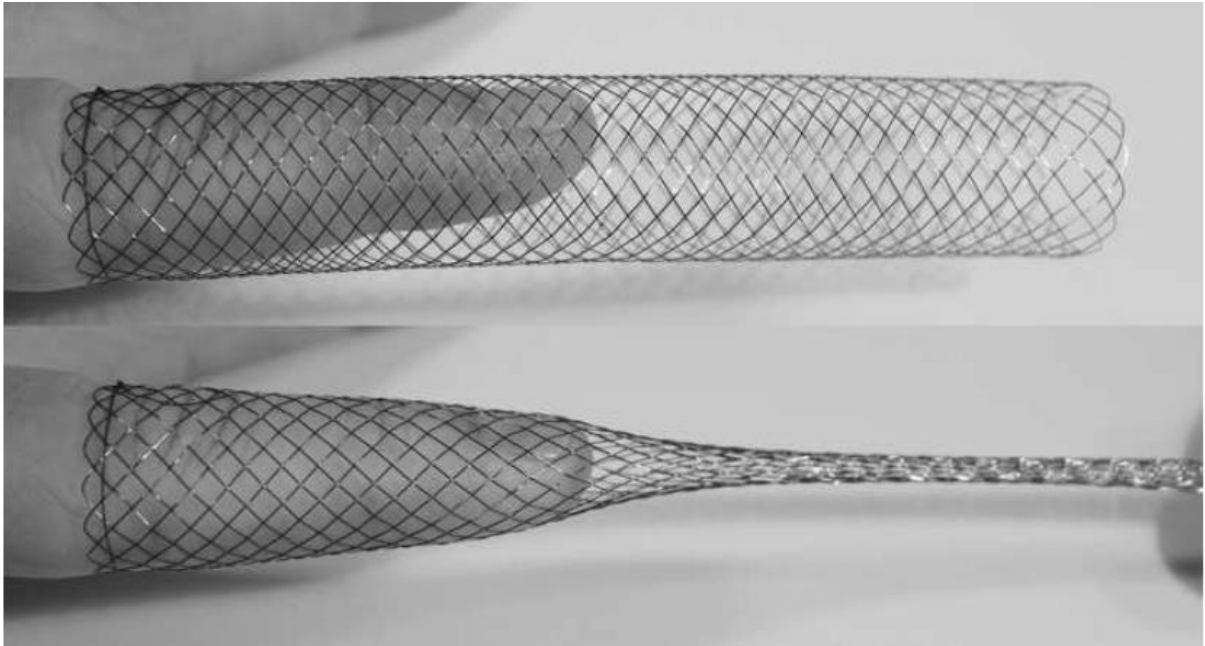


Figure 2: “Finger catcher” effect of a braided stent. On traction the stent lengthens and constricts, which is a useful feature, when removing a stent.

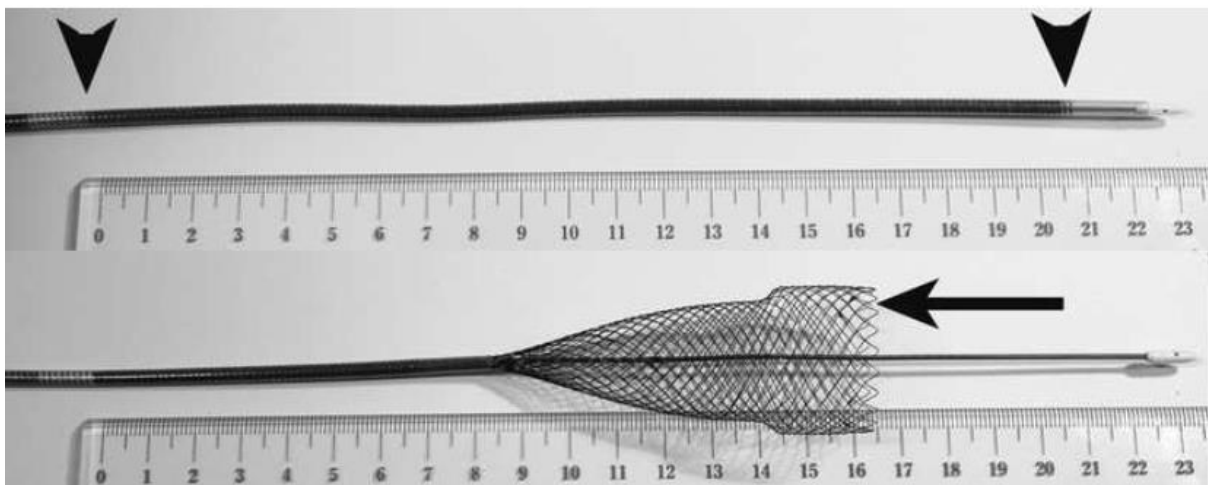


Figure 3: Shortening of a braided stent. Top: A 25x100mm colonic stent measures just over 20cm in the 10Fr. delivery sheath (arrowheads). Bottom: The stent shortens from the distal end on deployment (arrow).

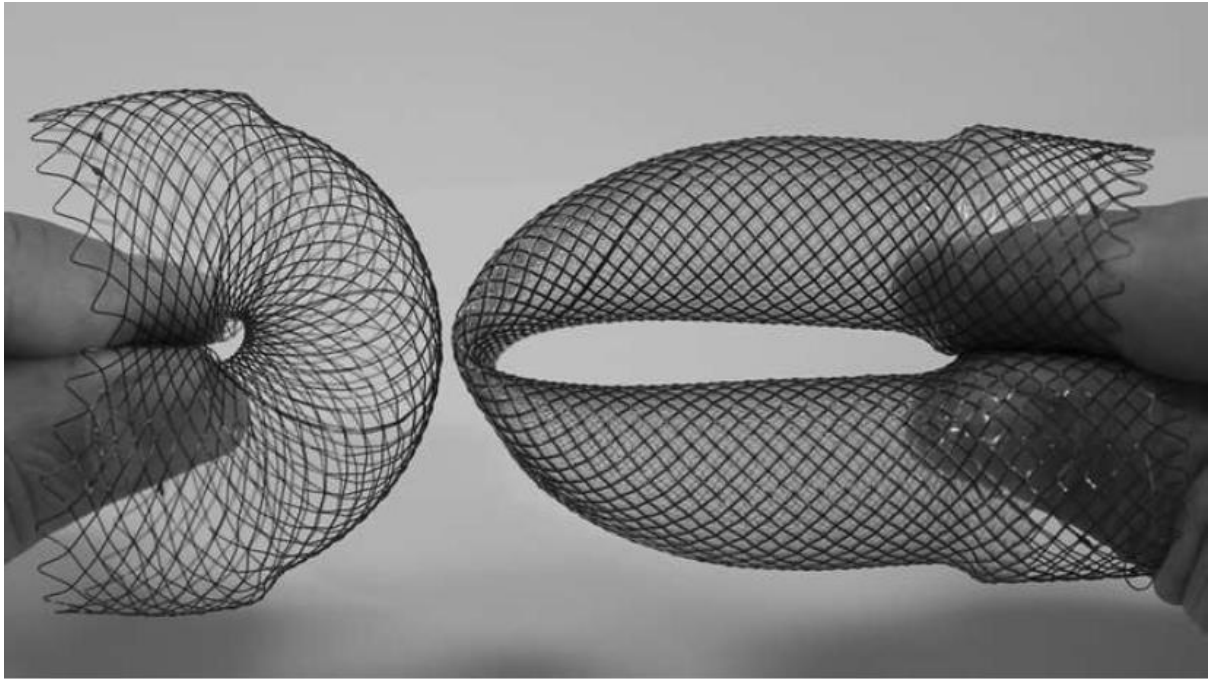


Figure 4: Bare and silicone covered versions of the same braided stent: The silicone-dipping has fixed the wires together and the stent kinks on flexion.

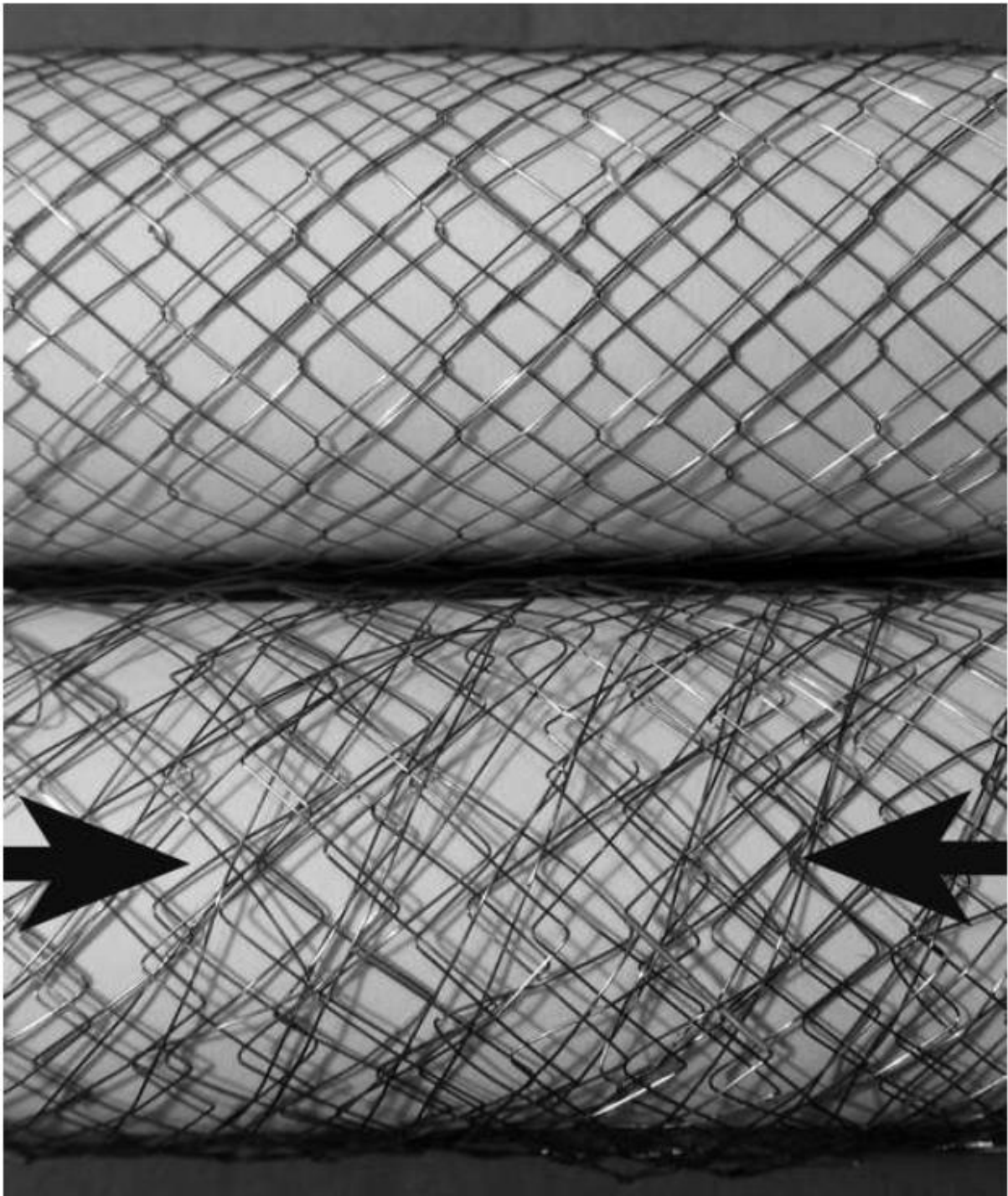


Figure 5: Knitted stent behavior. Top: relaxed stent, Bottom: compressed stent. Longitudinal compression (arrows) results in axial displacement of the wires, accommodating the forces.

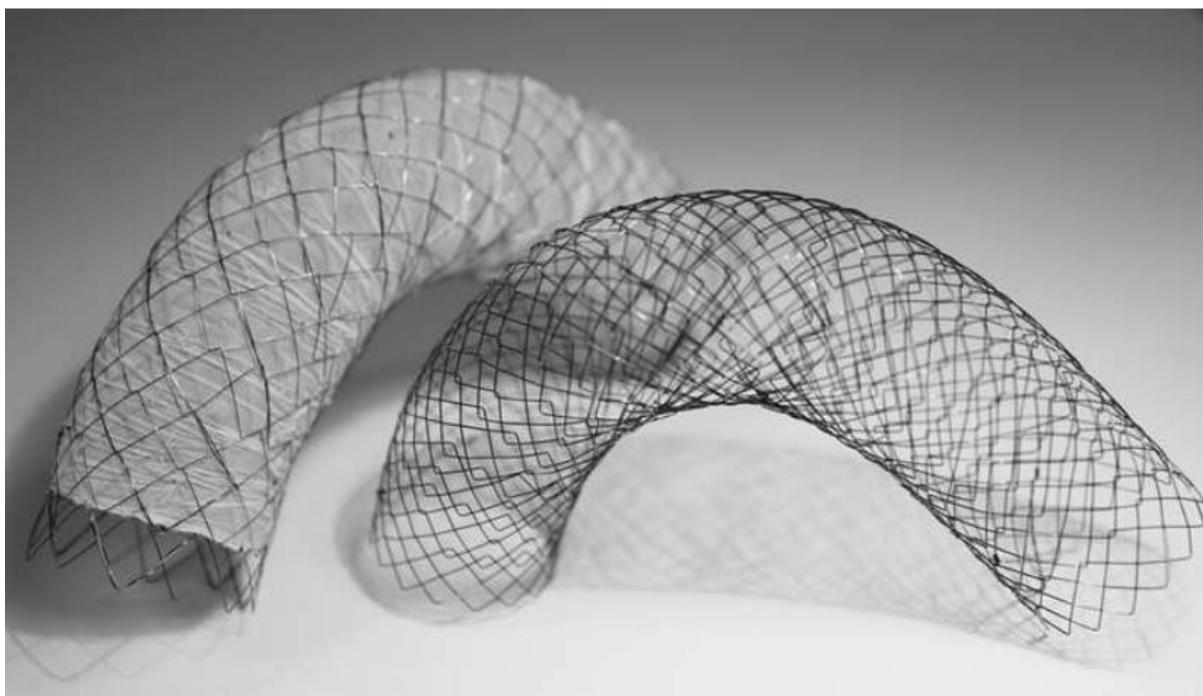


Figure 6: Conformability of double knitted stents: The lack of straightening forces is demonstrated by both bare and covered configurations.

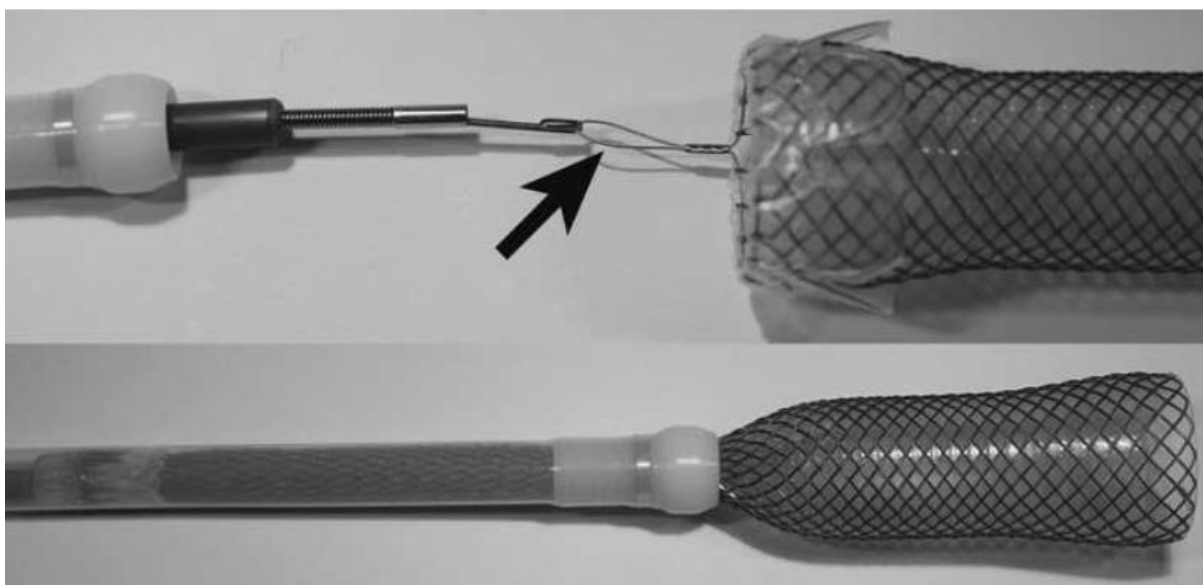


Figure 7: Stent extractor (Ella-CS). Top: Capture of the removal wire (arrow), Bottom: Withdrawal into the removal sheath

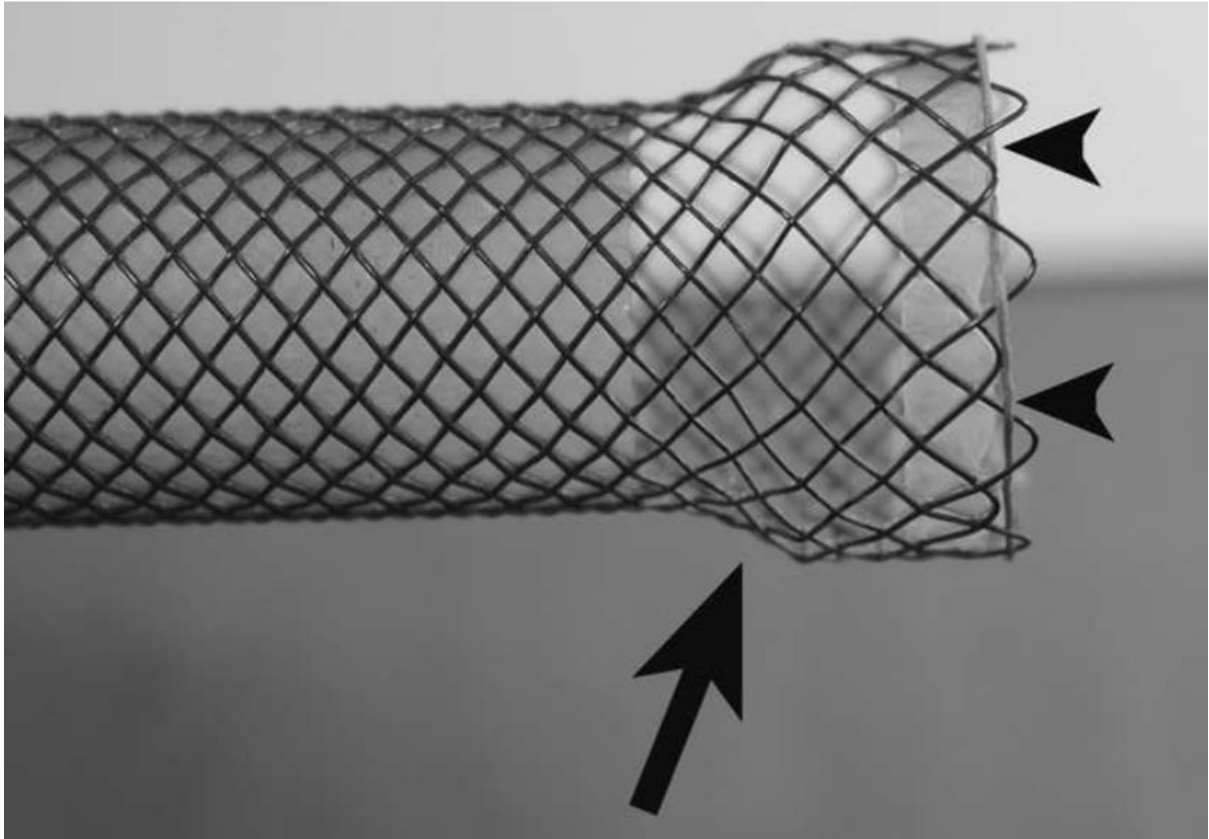


Figure 8: Partially covered stent (Wallflex, Boston Scientific, Marlborough, Mass., USA): The stent head consists mostly of bare metal (arrow). Note the purse string (arrowheads), which is only designed for stent repositioning immediately after insertion, but not for removal of an established stent.



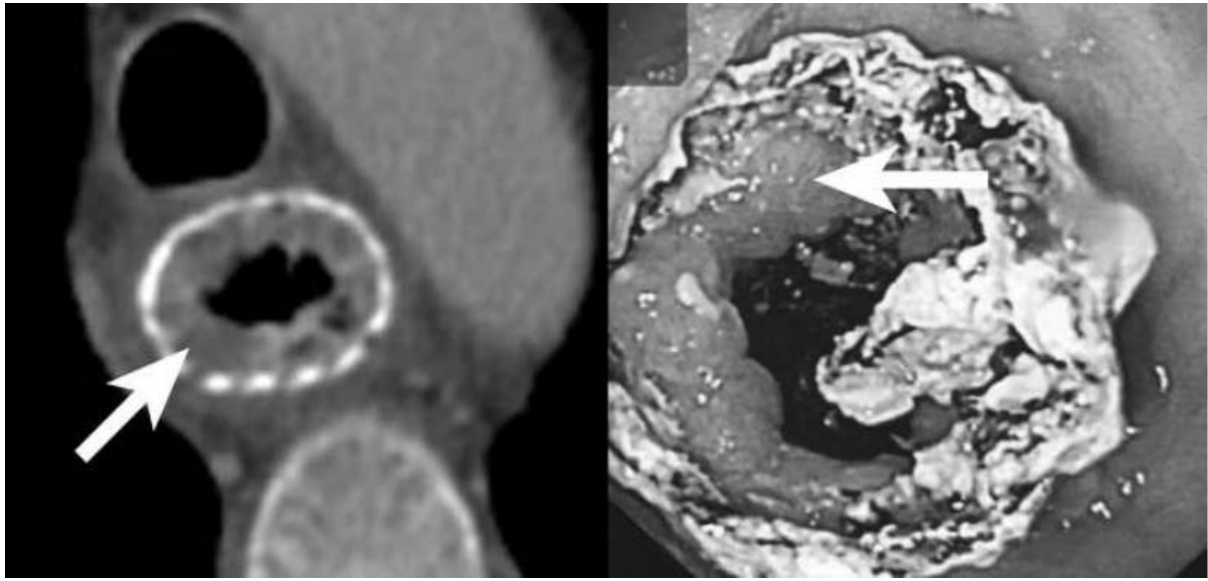


Figure 9: Left: Axial CT showing circumferential tumor ingrowth (arrow) indicating cover failure.

Right: Endoscopic view of a different patient with a perished stent after 3 months.

The silicone membrane has disintegrated, allowing tissue ingrowth (arrow). Removal was not attempted, swallowing was re-established by coaxial placement of a further stent.

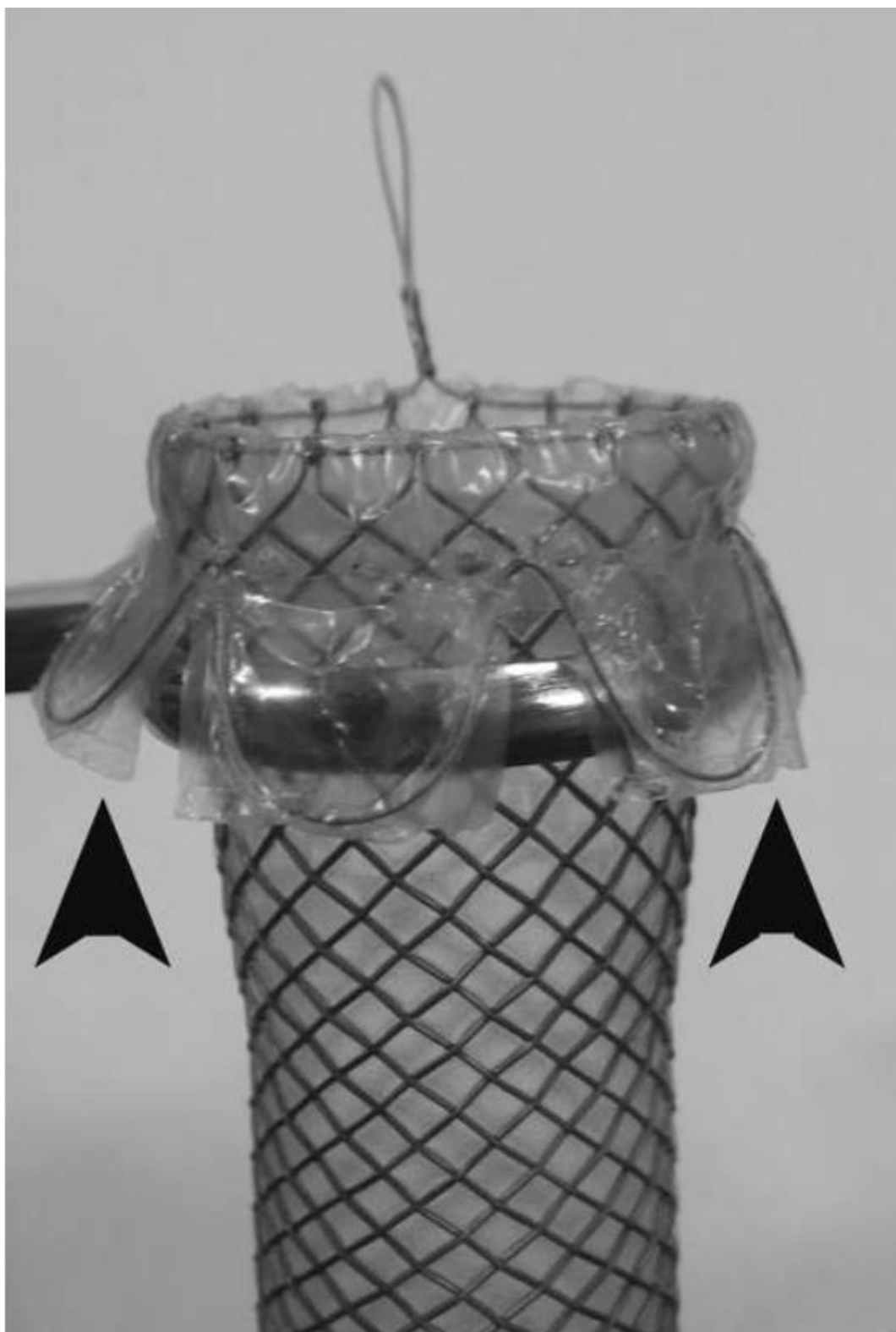


Figure 10: Anti-migration collar (arrowheads), providing mechanical anchoring above the stricture (Ella-HV *plus*, Ella-CS, Hradec Kralove, Czech Republic).

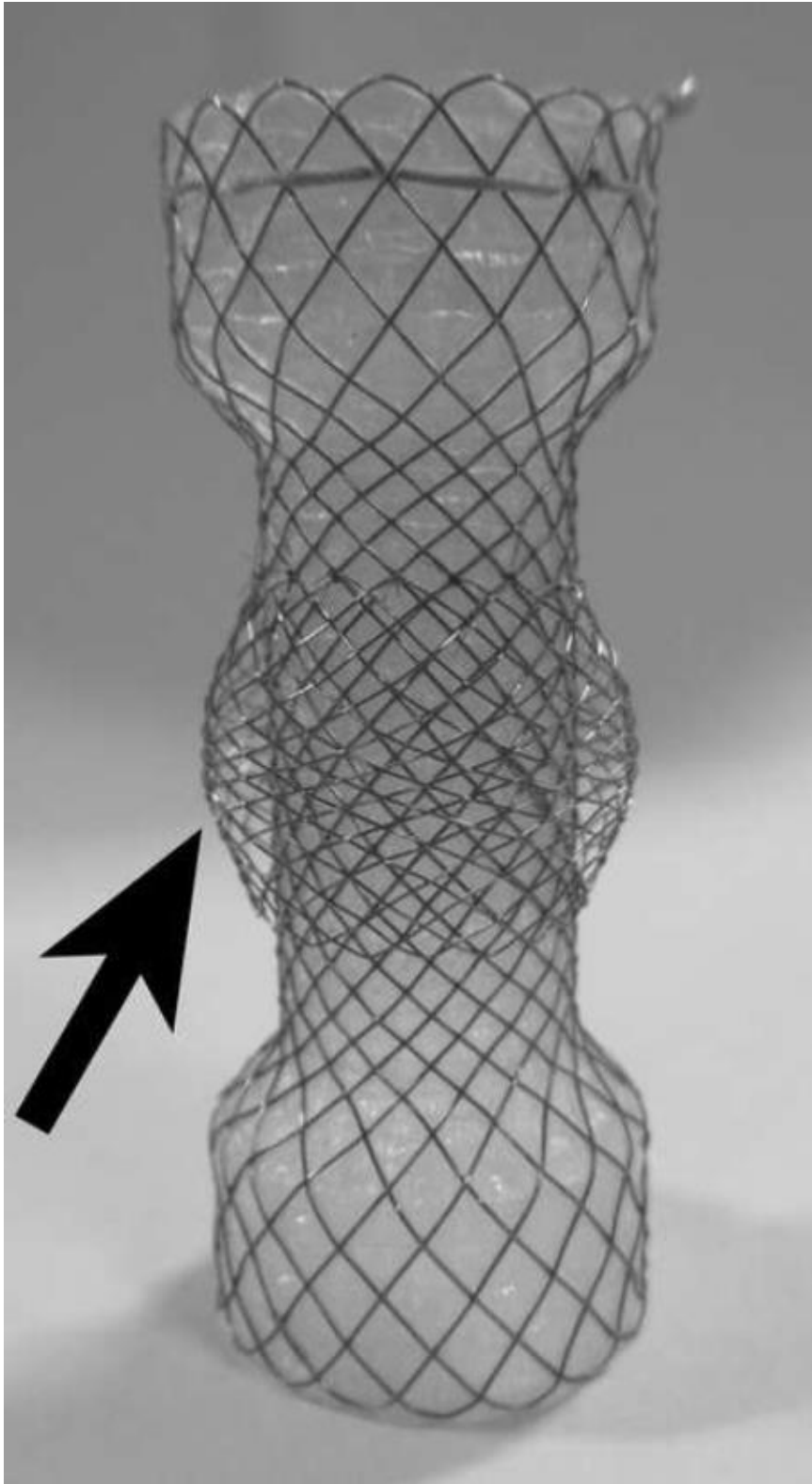


Figure 11: Double esophageal stent. The outer bare segment (arrowheads) is supposed to embed in the tumor (Niti-S, TaeWoong, Gyeonggi-Do, Korea).

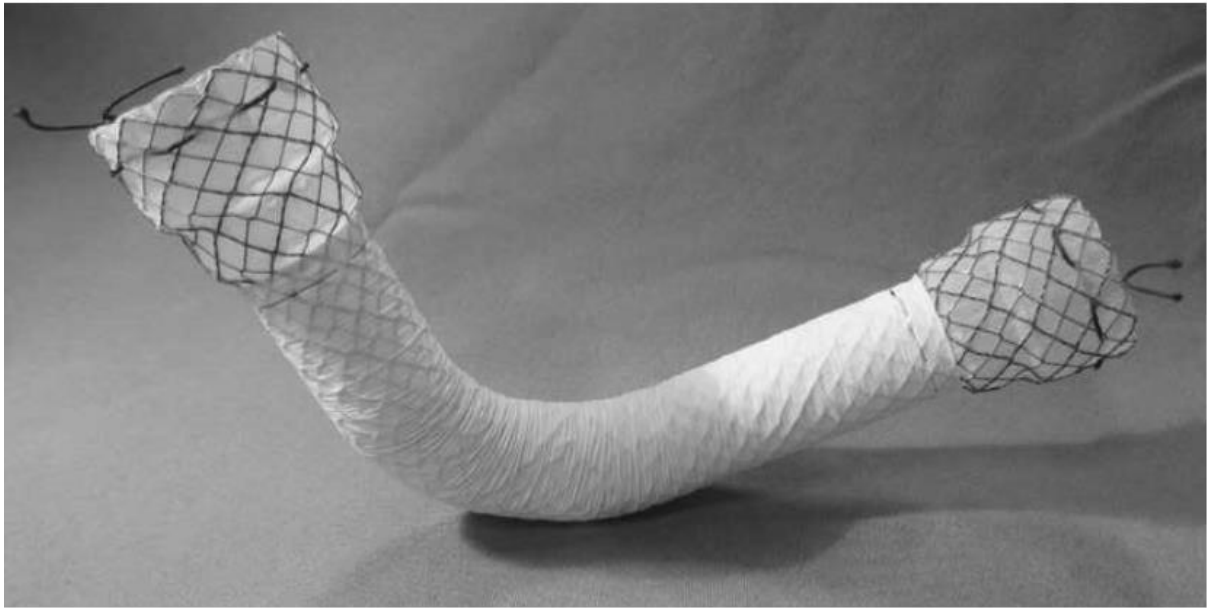


Figure 12: Knitted esophageal stent with silicone-dipped heads, but an ePTFE membrane externally covering the skeleton, thus retaining conformability (Egis, S&G Biotech, Gyeonggi-Do, Korea).

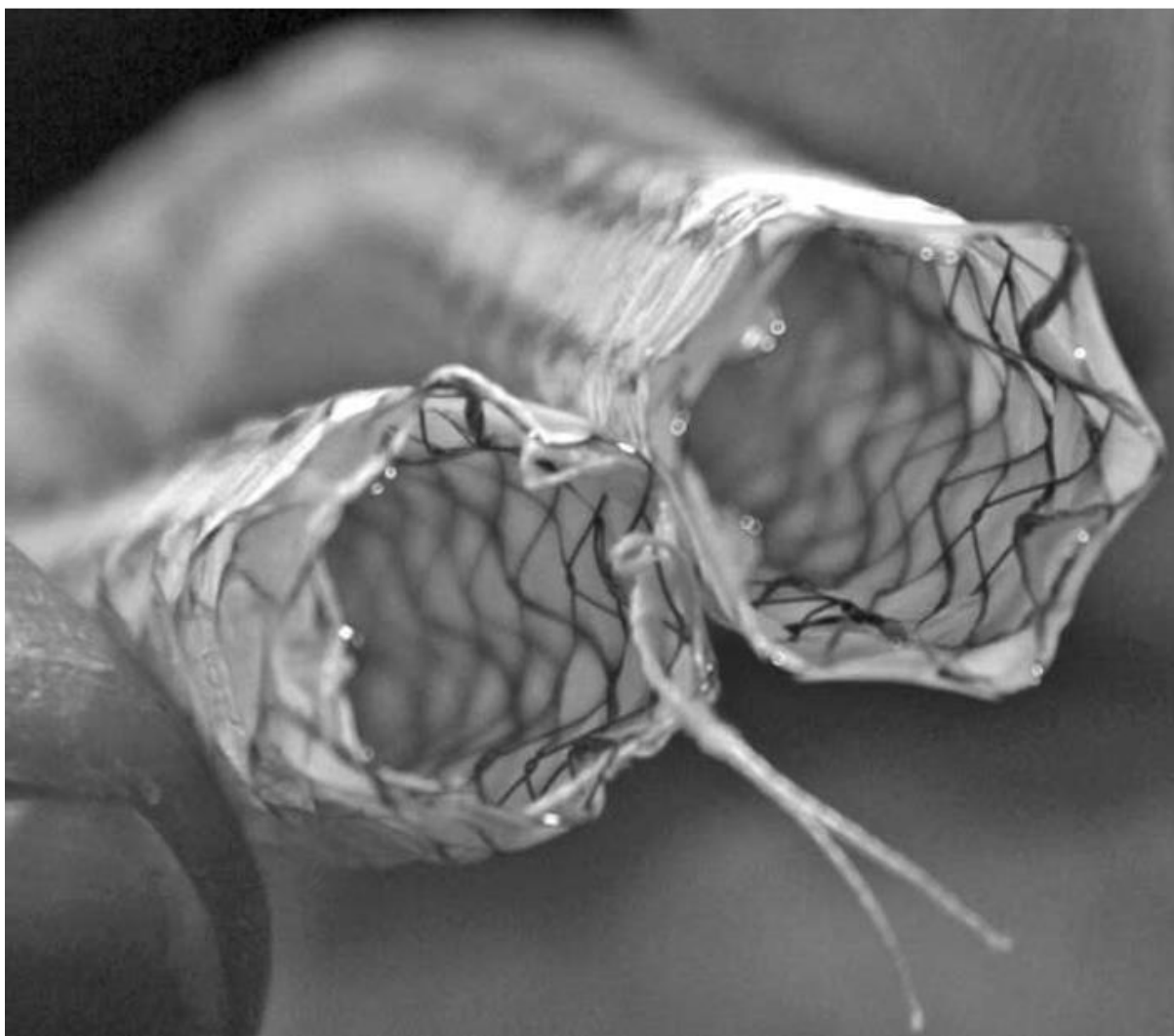


Figure 13: Corrugated cross-section of a knitted stent covered with an ePTFE membrane (Flower stent, S&G Biotech, Gyeonggi-Do, Korea).

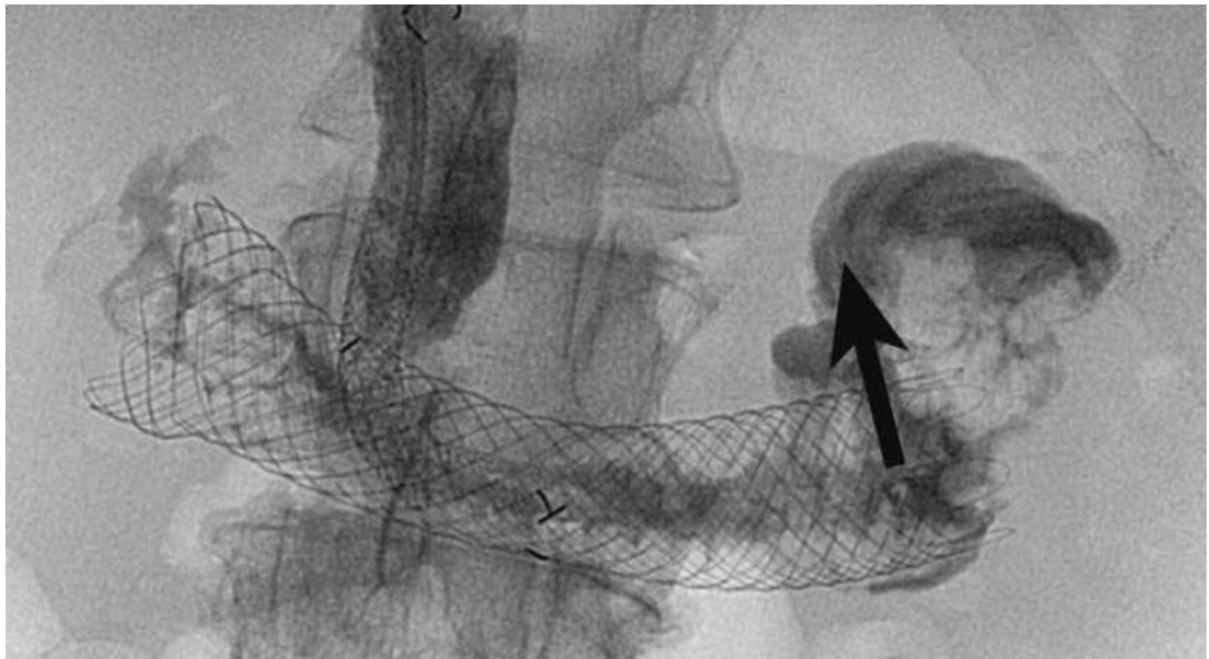
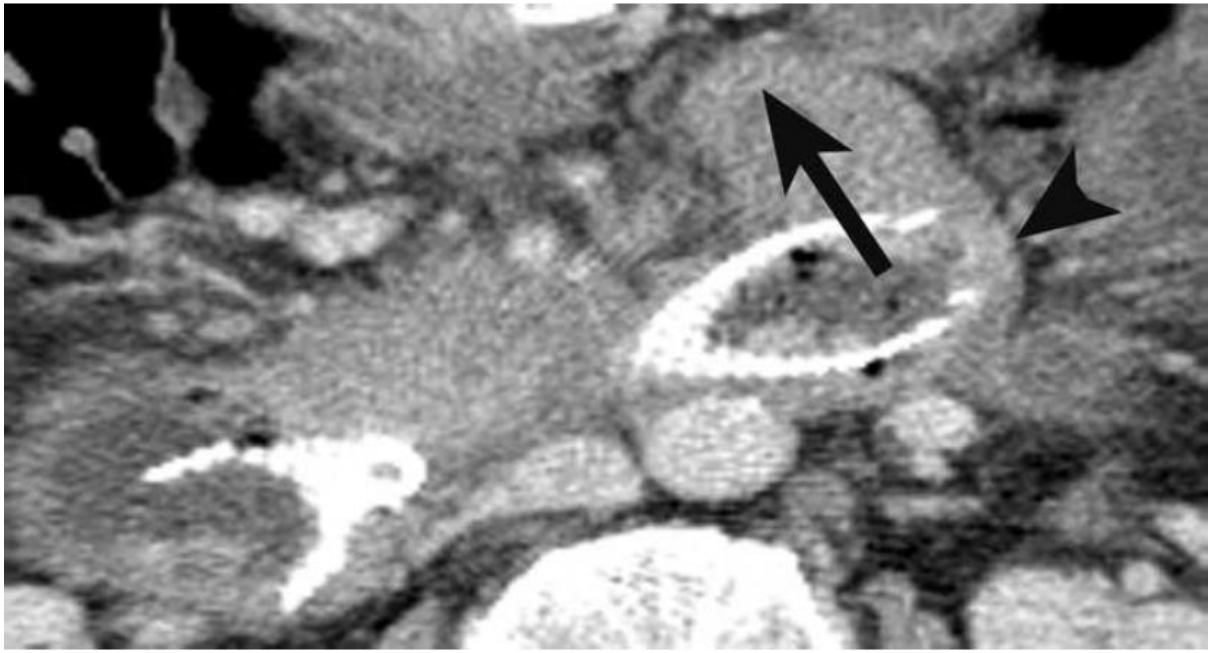


Figure 14: Poor functional result from a rigid stent. Braided duodenal stent with distal end embedded in D3/D4 flexure.

A, CT: The distal stent end is impacted on the duodenal wall (arrowhead), as it cannot follow the 90° anterior course of the distal duodenum (arrow).

B, Percutaneous cholangiogram: The contrast has to pass through the mesh of the stent (arrow), as the bowel wall is stretched over the stent exit.

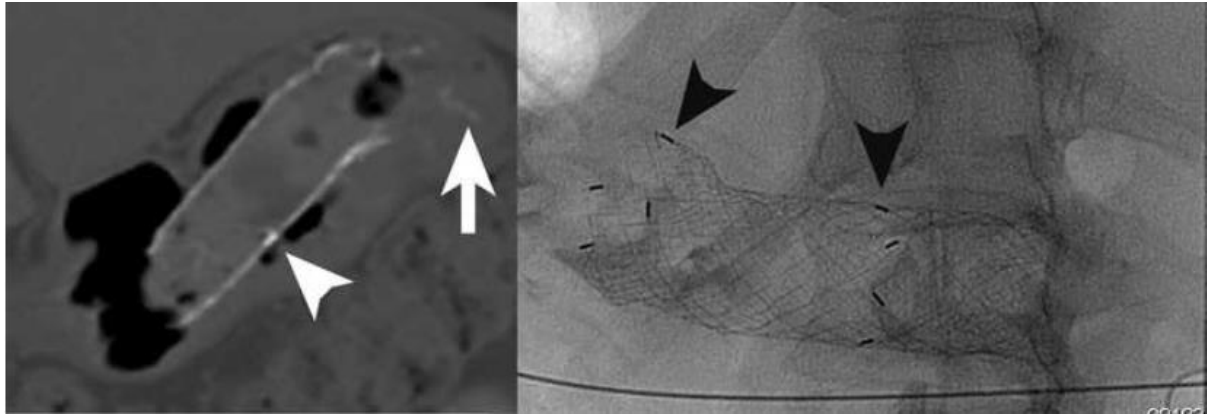


Figure 15: Stent fracture

A, CT showing a migrated and transected esophageal stent. Wire fragments are seen around the upper portion (arrow) and the lower head is missing. Arrowhead: middle stent marker.

B, The same patient undergoing re-stenting. The top and middle markers of the migrated stent are evident (arrowheads), the distal set is missing.